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| 09/552,272 | 04/19/2000 | Li Fang | 1113CIP4PCTUS00 | 3198 |

35811 7590 05/31/2007
IP GROUP OF DLA PIPER US LLP
ONE LIBERTY PLACE
1650 MARKET ST, SUITE 4900
PHILADELPHIA, PA 19103

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| EXAMINER |
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EPFS FORD, JANET L

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| ART UNIT | PAPER NUMBER |
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1633

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05/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/552,272

Applicant(s)

FANG ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,10,14-19,23-28,32-37,50 and 52-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5,6,10,14-19,23-28,32-37,50 and 53 is/are allowed.
- 6) ☒ Claim(s) 52,54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2.

Response to Arguments

Claim Rejections - 35 USC § 112

3. Claims 52, and 54-55 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.

4. Applicant's arguments filed 3-09-07 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that "[C]laim 52 is drawn to the expression of a heterologous gene under the control of one of the cold shock inducible regulatory elements of the specific SEQ ID NOs recited in claim 50 (i.e. SEQ ID NOs: 49, 50 or particularly recited portions of SEQ ID NO: 55). Because Claim 52 includes use of these specific cold shock inducible elements, and the specification provides full written description of the step of inserting a heterologous gene into a vector, one skilled in the art in possession of the Applicant's specification would understand that the inventors had full possession of the claimed subject matter at the time the application was filed. Additionally, the Applicants believe that the rejection of Claims 54 and 55 is due to their dependence on rejected Claim 52, as well as the

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alleged indefinite terminology in Claim 55.” Based on the foregoing reasoning Applicants concluded that due to the amendment of 3-09-07, it is believed that Claims 52, 54, and 55 are in condition for allowance.

Contrary to Applicant’s assertions, although the scope of the instant claims encompasses the specific sequence elements of SEQ ID NO: 49, 50 or particularly recited portions of SEQ ID NO: 55, the instant claims also encompass a genus of heterologous genes that are regulated by these elements. The specification as filed, and the prior art as of the filing date of the instant specification describe the structures of *E. coli* cspA, cspB, and the csdA genes. However, other than the cspA, cspB, and the csdA genes, neither the specification as filed, nor the prior art, provides a sufficient description of the full scope of nucleic acid sequence structures encoding cold-shock inducible genes, or genes that are regulated by some other mechanism by SEQ ID NO: 49, 50 or particularly recited portions of SEQ ID NO: 55. Since there is no clear correlation between the structures of genes that are potentially regulated by these sequence elements, the skilled artisan is left to further *de novo* experimentation to discover the full scope of nucleic acids that function as cold-shock inducible genes, or genes that are regulated by the sequence elements recited in the instant claims. As stated in the prior Office action, MPEP § 2163: “[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.”

5. The rejection of claims 20-21, 38-40, 44-46, and 55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment to the claims.

Conclusion

6. Claims 1, 5-6, 10, 14-19, 23-28, 32-37, 50 and 53 are allowable.

7. Claims 52, and 54-55 remain rejected for the reasons set forth above.


8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE